UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.usplo.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/623,957	07/21/2003	Wesley D. Johnson	1842-0019	6059	
28078 MAGINOT. M	7590 04/03/2007 IOORE & BECK, LLP		EXAMINER		
CHASE TOWER			COMSTOCK, DAVID C		
111 MONUMENT CIRCLE SUITE 3250			ART UNIT	PAPER NUMBER	
INDIANAPOLIS, IN 46204					
SHORTENED STATUTOR	RY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MO	ONTHS	04/03/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

				_			
		Application No.	Applicant(s)				
Office Action Summan		10/623,957	JOHNSON ET AL.				
	Office Action Summary	Examiner	Art Unit	•			
		David Comstock	3733				
Period f	The MAILING DATE of this communication app or Reply	pears on the cover sh	eet with the correspondence address				
WHII - Exte afte - If No - Fail Any	IORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING Digensions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. O period for reply is specified above, the maximum statutory period vure to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing led patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMN 36(a). In no event, however, will apply and will expire SIX and the application to be	MUNICATION. may a reply be timely filed 6) MONTHS from the mailing date of this communic ome ABANDONED (35 U.S.C. § 133).				
Status							
1) 又	Responsive to communication(s) filed on 21 M	larch 2007					
•		action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Disposit	ion of Claims		·				
4) 🖂	Claim(s) <u>192-197 and 209-224</u> is/are pending i	in the application.					
,—	4a) Of the above claim(s) is/are withdrawn from consideration.						
⁻5)□	Claim(s) is/are allowed.						
6)⊠	6) Claim(s) 192-197,209-215,217 and 222-224 is/are rejected.						
	Claim(s) 216 and 218-221 is/are objected to.						
8)[Claim(s) are subject to restriction and/or	r election requireme	nt.				
Applicat	ion Papers						
9)🖂	The specification is objected to by the Examine	r.					
10)⊠ The drawing(s) filed on <u>21 July 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.							
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11)	The oath or declaration is objected to by the Ex	aminer. Note the att	ached Office Action or form PTO-152	<u> </u>			
Priority	under 35 U.S.C. § 119						
	Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority documents	s have been receive	d.				
	2. Certified copies of the priority documents	s have been received	d in Application No				
	3. Copies of the certified copies of the prior		-				
	application from the International Bureau (PCT Rule 17.2(a)).						
- ;	See the attached detailed Office action for a list	of the certified copie	s not received.				
Attachmen	t(s)						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)							
	ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08)		er No(s)/Mail Date ce of Informal Patent Application				
	er No(s)/Mail Date	6) 🔲 Othe					

DETAILED ACTION

Response to Amendment

The terminal disclaimer filed on 21 March 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Pat. No. 6,595,998 has been reviewed and is accepted. The terminal disclaimer has been recorded. However, upon further consideration, new grounds of rejection have been discovered and are set forth below. Accordingly, the finality of the previous outstanding action is withdrawn.

Priority

The priority information in the first sentence of the Specification (as updated in the Preliminary Amendment filed 21 July 2003) requires further updating to reflect that parent application 09/872,905 has matured into U.S. Pat. No. 6,595,998.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 192-195, 209, 210, 212-214, 217 and 222-224 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner (5,702,454).

Page 3

Art Unit: 3733

Baumgartner discloses a method of accessing an intradiscal space 5 via an elongated access channel 6 and providing an expandable structure comprising at least a top element 7, a bottom element 7 and a plurality of intermediate elements 7 through the channel to the intradiscal space (see, e.g., Figs. 1 and 2). The top element is configured to contact the upper vertebral body 2, the bottom element is configured to contact the lower vertebral body 1, and the intermediate elements are configured to reside between the top and bottom elements. The intermediate elements are introduced consecutively and individually into the central intervertebral space, such that as they slide between the top and bottom elements, the top and bottom elements move apart to support (and distract) the vertebrae. The elements 7 may be considered to be configured for interlocking coupling via ducts 14 and a common support 20 (see, e.g., Fig. 6 and col. 5, lines 22-33). The top, bottom and intermediate elements may have different dimensions (see, e.g., col. 2, lines 8 and 9). The elements may comprise solid, rigid elements (see, e.g., col. 2, lines 12-14). The elements are formed of "implant materials" such as, for example, polyurethane and/or hydrogel (see, e.g., col. 2, lines 51-57). The space is accessed by a posterior or posterior lateral approach (see, e.g., Fig. 1). The sloping, spherical upper surfaces of the elements act as lifting surfaces to other elements thereagainst. With regard to claim 224, the active step is "monitoring the tension in the annulus of the disc," while the language "as an indication of said stability" only addresses the reason for performing the active step. As such, the latter is not given patentable weight in a claim drawn to a method. Moreover, the process of Baumgartner inherently includes "monitoring" the tension in the annulus at least

Application/Control Number: 10/623,957

Art Unit: 3733

because the same is necessary to determine when the space is sufficiently filled and the device is capable of serving as a support structure (see, e.g., col. 5, lines 53-60).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 196 and 197 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner (5,702,454).

Baumgartner discloses that the elements may have different dimensions but does not explicitly recite that the top or bottom elements have a greater area than the intermediate elements. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the differently sized elements in locations such that the top or bottom elements are larger than the intermediate elements, since it has been held that mere relocation of parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. Moreover, it is noted that a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claims 211 and 215 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner (5,702,454) in view of Kuslich et al. (7,025,771).

Baumgartner discloses the claimed invention except for explicitly disclosing the use of a bone filler material. Kuslich et al. disclose a similar device comprising various combinations of bone replacement materials 26 that comprise bone filler material to provide a desired physiological response and improve the outcome of the surgical procedure (see, e.g., Fig. 3 and col. 2, lines 33-46). As such, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have also provided the device of Baumgartner with a bone filler material, in view of Kuslich et al., in order to provide a desired physiological response and improve the outcome of the surgical procedure.

Allowable Subject Matter

Claims 216 and 218-221 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. Please leave a detailed voice message if examiner is unavailable. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/623,957

Art Unit: 3733

Page 6

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. Comstock

EDUARDO/C/ROBERT SUPERVISORY PATENT EXAMINER